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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 863,777	05 23 2001	James W. Fett	10498-00012	2435

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EXAMINER

EPPS, JANET L.

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11 14 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

<b>Application No.</b> 09/863,777  <b>Examiner</b> Janet L Epps-Ford, Ph.D.	<b>Applicant(s)</b> FETT ET AL.  <b>Art Unit</b> 1635
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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### **Status**

- 1) Responsive to communication(s) filed on 04 September 2002.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

- 4) Claim(s) 1-14 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9, 11, 13, 14 and 24-28 is/are rejected.
- 7) Claim(s) 10 and 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### **Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### *Response to Arguments*

#### *Claim Rejections - 35 USC § 112*

1. Claims 1-9, 11 and 13 remain rejected, and claims 24-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 3-19-2002.

Applicant's arguments filed 6-12-02 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that "Applicants are claiming compounds that inhibit the expression of angiogenin. The compounds have a base sequence complementary to a target portion of a nucleic acid encoding angiogenin. Applicants provide the nucleic acid encoding angiogenin. Applicants also teach base complementarity. Based on this information, one of skill in the art will be able to readily envision compounds having a base sequence complementary to a target portion of a nucleic acid encoding angiogenin and a list of such compounds is unnecessary."

However, contrary to Applicant's assertions, the instant claims read on antisense oligonucleotides targeting angiogenin gene sequences from any species and all polymorphic and allelic variants of said angiogenin gene sequences. However, the antisense oligonucleotides described in the specification as filed, are designed based upon the structure of a single species of angiogenin nucleic acid sequence. Specifically, see Figure 1, wherein Applicants disclose the sequence of human angiogenin. Therefore, as stated in the prior office action, Applicant's

disclosure combined with what is known in the prior art, are not sufficient to describe the claimed genus of compounds and compositions for inhibiting expression of all species of angiogenin, including all polymorphic and allelic variants of angiogenin.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

In the instant case, Applicants are only in possession of antisense oligonucleotides targeting the nucleic acid sequence of human angiogenin as set forth in Figure 1 of the specification as filed. Further experimentation is required in order for applicant's to determine the sequence of all other polymorphic and allelic variants of angiogenin and furthermore identify antisense oligonucleotides targeting these polymorphic and allelic variants of angiogenin nucleic acid.

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2. Claims 9, and 13-14 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9, and 13-14 recite the broad recitation "O, S, N-alkyl," and the claim also recites, for example: SCH<sub>2</sub>, and OCH<sub>3</sub> which is the narrower statement of the range/limitation. Additionally, these claims also recite the term "conjugate," however every other modification recited in these claims may also be considered a conjugate. Moreover, the majority of the modifications recited in these claims may also function to improve the pharmacokinetic or phamacodynamic properties of oligonucleotides.

b) Line 3 of claim 9 inappropriately recites underlining which directs the insertion of a comma, this instruction should not be present in the clean-copy of the claims as per 37 CFR 1.121(c).

c) Claim 9 recites the term "OCH<sub>6</sub>CH<sub>3</sub>," this term is chemically improper, the correct term is likely to be "OCH<sub>2</sub>CH<sub>3</sub>."

***Claim Rejections - 35 USC § 103***

3. Claims 1-9, 11 and 13 remain rejected, and claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallee et al., in view of Olson et al., Milligan et al., Burch, Anderson et al., and Artavanis-Tsakonas et al. for the reasons of record set forth in the Official Action mailed 3-19-2002.

Applicant's arguments filed 6-12-02 have been fully considered but they are not persuasive. Applicants argue that the primary reference of Vallee et al. does not teach an antisense approach to inhibiting expression of angiogenin. Applicants argue that the reference of Olson et al., does not provide motivation to look to an antisense approach. Applicants argue that the references of Milligan et al., Burch, Artavanis-Tsakonas et al., and Anderson, are not concerned with angiogenin, in particular.

Applicants' arguments have been considered but are not persuasive because although Milligan et al. do not explicitly teach angiogenin inhibition, Milligan teaches making antisense oligonucleotides if the gene sequence is known. Vallee et al. provide the gene sequence of angiogenin. One of ordinary skill in the art would have been motivated to further elucidate the function of angiogenin by inhibiting angiogenin gene expression because Olson et al., which does not explicitly teach antisense oligonucleotides that target angiogenin, does suggest inhibiting angiogenin in order to assess the role of angiogenin in tumor growth. Thus what was known particularly about angiogenin and tumor growth, as taught by the references of Vallee et al. and Olson et al., combined with the teaching of Milligan et al. for employing the antisense art,

and the disclosures of Burch, Artavanis-Tsakonas et al., and Anderson for modifying oligonucleotides in general, render claims 1-9, 11, 13, and claims 24-28 unpatentable under 35 U.S.C. 103(a).

*Claim Objections*

4. Claims 10 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

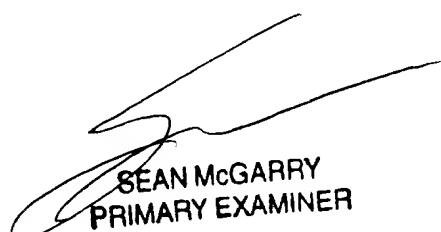
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

JLE  
November 12, 2002



SEAN McGARRY  
PRIMARY EXAMINER  
1635